

### **III. Remarks**

Claims 1-23 and 38-51 were previously pending. No claims are currently canceled or added.

Applicant appreciates the indication that claims 17, 18, 23, 41-44, and 47-51 would be allowable if rewritten in independent form. To that end, claims 17, 23, 41, and 47 have been rewritten in independent form. Claims 18, 42-44, and 48-51 depend from and further limit claims 17, 41, and 47. Therefore, claims 17, 18, 23, 41-44, and 47-51 are allowable.

Reconsideration of claims 1-23 and 38-51 is requested in light of the above amendments and the following remarks.

#### **Claim Objections**

Claims 17 and 23 were objected to because of minor typographical errors. Applicant has amended these claims to correct these errors.

#### **§102 Rejection**

**Claim 1** stands rejected under 35 U.S.C. §102(b) as being anticipated by the article written by Karladani et al. (“the Karladani article”).

The PTO provides in MPEP § 2131 that

“[t]o anticipate a claim, the reference must teach every element of the claim....”

Therefore, to sustain this rejection the Karladani article must teach all of the claimed elements of amended independent claim 1. However, the Karladani article at least fails to disclose “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia with the patient’s leg extended” as recited. The Office Action asserts that the “Karladani [reference] disclose[s] insertion of an intramedullary nail of ‘fixation member’ in a tibia by gaining supra patellar surgical access (Fig. 3 and page 737).” However, it is clear from the written description of the surgical approach and the

illustration of Fig. 2 that the insertion approach described by the Karladani reference does not provide supra patella surgical access as required. Rather, the Karladani reference discloses medial or lateral surgical access relative to the patella. For example, the Karladani reference states:

**“We describe a new approach, in which the skin incision is located on either the medial or lateral side of the patella and nailing is performed percutaneously.”** Page 736.

**“The patient should be placed in a standard position. After skin preparation and draping, a 3-4 cm incision is made medial or lateral to the patella.”** Page 737.

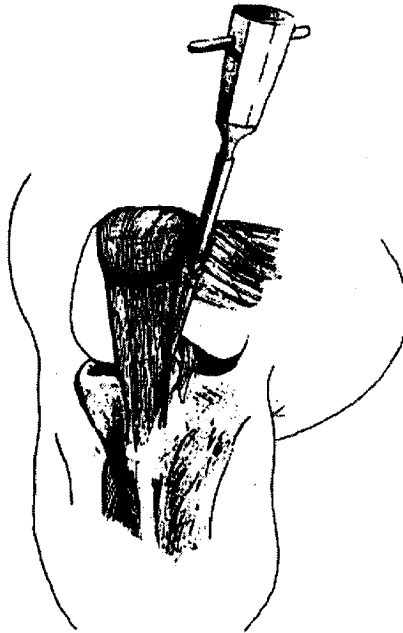


Fig. 2. Straight awl is passed into the tunnel to penetrate the tibial cortex.

While the Karladani reference states that the incision “extends from the base of the patella to 1 cm above the apex of the patella,” it is clear from the accompanying description that this provides medial or lateral access relative to the patella, not supra patella access as recited by claim 1.

Further, the Karladani reference fails to disclose gaining surgical access “with the patient’s leg extended,” as recited in amended claim 1. Rather, the Karladani reference

states that “[t]he patient should be placed in a standard position.” As shown in Figs. 2 and 3 of the Karladani reference, the standard position is with the knee bent such that the tibia extends substantially perpendicular to the femur. This is consistent with the excerpt from *Campbell’s Operative Orthopaedics* (7<sup>th</sup> Edition) previously submitted by Applicant for consideration by the Examiner, where Figs. 44-37 through 44-42 and the corresponding text illustrate the insertion of an intramedullary nail into the intramedullary canal of a tibia using an infra-patellar surgical access with the patient’s knee bent.

Accordingly, for at least these reasons the Karladani reference fails to teach all of the recited elements of independent claim 1. Therefore, Applicant respectfully requests that the §102 rejection of claim 1 over the Karladani reference be withdrawn.

### **§103 Rejections**

**Claims 2-6, 11, 13, 19, 21, 38-40, 45, and 46** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Karladani reference in view of U.S. Patent No. 5,624,447 to Myers (“the Myers patent”). **Claim 7** stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Karladani reference in view of the Myers patent as applied to claim 3, in further view of U.S. Patent No. 6,419,678 to Asfora (“the Asfora patent”). **Claims 8 and 9** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Karladani reference in view of the Myers patent as applied to claim 3, in further view of U.S. Patent No. 6,656,189 to Wilson et al. (“the Wilson patent”).

Applicants respectfully traverse these rejections on the grounds that these references are defective in establishing a prima facie case of obviousness.

As the PTO recognizes in MPEP § 2142:

“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”

It is submitted that in the present case the examiner has not factually supported a prima facie case of obviousness.

The PTO provides in MPEP §2142:

“[T]he examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention ‘as a whole’ would have been obvious at that time to that person.”

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. In the current case, even when combined the Karladani reference and the Myers patent fail to teach or suggest the combination of elements recited in each claim.

With respect to claims 2-6, 11, and 13, these claims depend from and further limit independent claim 1. As shown above, the Karladani reference at least fails to teach “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia with the patient’s leg extended,” as recited by claim 1. Rather, the Karladani reference discloses gaining medial or lateral surgical access relative to the patella with the patient’s leg bent such that the tibia is substantially perpendicular to the femur. Similarly, the Myers patent fails to disclose gaining supra patella surgical access with the patient’s leg extended. Therefore, even when combined the Karladani reference and the Myers patent fail to teach all of the recited elements of independent claim 1. Claims 2-6, 11, and 13 depend from and further limit claim 1. Accordingly, the Karladani reference and the Myers patent, even when combined, fail to teach all of the recited elements of these claims.

Further, claims 7-9 indirectly depend from and further limit claim 1. However, the Asfora and Wilson patents applied to these claims also fail to teach “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia with the patient’s leg extended.” Accordingly, even when combined with the Karladani and

Myers references, these references do not teach all of the claimed limitations of claims 7-9 as well.

Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claims 2-9, 11, and 13. Therefore, Applicant requests that the §103 rejection of claims 2-9, 11, and 13 over the Karladani and Myers references be withdrawn.

With respect to independent claim 19, even when combined the Karladani reference and the Myers patent fail to disclose “creating a supra patella surgical access site.” As discussed in detail with respect to claim 1 above, the Karladani patent fails to disclose gaining supra patella surgical access. Rather, the Karladani patent discloses creating a medial or lateral surgical access site relative to the patella. The Myers patent also fails to disclose a supra patella surgical access site. Accordingly, even when combined these references fail to teach the recited limitations of independent claim 19. Claim 21 depends from and further limits claim 19. Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claims 19 and 21. Therefore, Applicant requests that the §103 rejection of claims 19 and 21 over the Karladani and Myers references be withdrawn.

With respect to independent claim 38, even when combined the Karladani reference and the Myers patent fail to disclose “creating a percutaneous incision, a majority of the incision being above a patella;” As discussed in detail with respect to claim 1 above, the incision described in the Karladani patent is medial or lateral to the patella. The Karladani patent simply fails to disclose a percutaneous incision with a majority of the incision being above the patella. The Myers patent also fails to disclose an incision above the patella as recited. Accordingly, even when combined these reference fail to teach the recited limitations of independent claim 38. Claims 39 and 40 depend from and further limit claim 38. Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claims 38-40. Therefore, Applicant requests that the §103 rejection of claims 38-40 over the Karladani and Myers references be withdrawn.

With respect to independent claim 45, even when combined the Karladani reference and the Myers patent fail to disclose “with the patient’s leg extended, inserting a sheath through the incision posterior to the patella such that a distal portion of the sheath is positioned adjacent a proximal portion of the tibia.” As discussed above with respect to claim 1, the Karladani reference discloses positioning the patient with a bent knee such that the tibia extends substantially perpendicular to the femur. The Myers patent also fails to disclose inserting a sheath posterior to the patella with the patient’s leg extended. Accordingly, even when combined these reference fail to teach the recited limitations of independent claim 45. Claim 46 depends from and further limits claim 45. Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claims 45 and 46. Therefore, Applicant requests that the §103 rejection of claims 45 and 46 over the Karladani and Myers references be withdrawn.

**Claims 10, 12, 14-16, and 22** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Karladani reference in view of U.S. Patent No. 6,270,499 to Leu et al. (“the Leu patent”). Applicants respectfully traverse these rejections on the grounds that these references are defective in establishing a prima facie case of obviousness.

In particular, claims 10, 12, and 14-16 depend from and further limit independent claim 1. As shown above, the Karladani reference at least fails to teach “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia with the patient’s leg extended,” as recited by claim 1. Rather, the Karladani reference discloses gaining medial or lateral surgical access relative to the patella with the patient’s leg bent such that the tibia is substantially perpendicular to the femur. Similarly, the Leu patent fails to disclose gaining supra patella surgical access with the patient’s leg extended. Therefore, even when combined the Karladani reference and the Leu patent fail to teach all of the recited elements of independent claim 1. Claims 10, 12, and 14-16 depend from and further limit claim 1. Accordingly, the Karladani reference and the Leu patent, even when combined, fail to teach all of the recited elements of these claims.


Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claims 10, 12, and 14-16. Therefore, Applicant requests that the §103 rejection of claims 10, 12, and 14-16 over the Karladani and Leu references be withdrawn.

Claim 22 depends from and further limits claim 19. However, claim 19 is not currently rejected over the combination of the Karladani reference and the Leu patent. In that regard, even when combined the Karladani and Leu references fail to disclose “creating a supra patella surgical access site; inserting a substantially tubular protective sheath posterior to a patella such that a distal end is adjacent a proximal end of the tibia; [and] accessing the intramedullary canal of the tibia utilizing a cutting tool guided by the protective sheath,” as recited by claim 19. Accordingly, for at least the same reasons the Karladni reference and the Leu patent, even when combined, fail to teach all of the recited elements of claim 22. Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claim 22 and Applicant requests that the §103 rejection of claim 22 over the Karladani and Leu references be withdrawn.

#### IV. Conclusion

It is believed that all pending claims 1-23 and 38-51 are in condition for allowance. An early indication of allowance of all claims is hereby requested. Should the Examiner decide that an interview would expedite prosecution, please contact the undersigned attorney.

Respectfully submitted,

  
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Karen D. Underwood